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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/329,002 06/08/99 MOONEY

C ECC-5062CIP2

EXAMINER

QM22/0328

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THANH, L	
ART UNIT	PAPER NUMBER

3763
DATE MAILED:

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03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/329,002

Applicant(s)

MOONEY ET AL.

Examiner

LoAn H Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 12-16, 19, 25, 38-59 and 71-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 17-18, 20-24, 26-37, 60-70, 77-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3,6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species A and 5 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the method claims dependent on claim 60 has the same structure as the device of claim 1 would require only one search. The Examiner is in agreement and will consider the method claims as elected.
2. Applicant has not argued which claim is generic and thus, the Examiner is maintaining there are no generic claims.
3. Claims 75-76 are withdrawn from further consideration since they depend on non-elected claims 71 and 75 respectively.

The requirement is still deemed proper and is therefore made FINAL.

An action on the merits now follows.

Drawings

4. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.
5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the outer tube made from a different material that the at least one flexible wall (claims 26, 79) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Specification

a. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

The specification is objected to under 37 CFR 1.71 because there is a lack of enablement with the connection of the junction housing in relation to the outer tube and the lumens therein. It is unclear whether applicant has just confused the proximal and distal end locations. Correction of this would result in the Examiner withdrawing this rejection. See 112, 2nd paragraph rejection below. See comments regarding claims with subject matter regarding the main channel in the junction housing continues past the channel to an opening in the junction housing.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-11, 17-29, 30-37, 60-70, 77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear what applicant intended by "wherein the device lumen has cross-sectional areas". Applicant has only set forth the cross sectional area of the outer tube and the first cross-sectional area of the device lumen. Further, it is unclear what the second cross-sectional area is. Further still, it is unclear what the flexed positions are. And whether there is/are one or more flexed positions and only one relaxed position. Further, it is unclear what "first cross sectional area " in line 17 applicant intended. It is unclear whether it is the one of the outer tube or the one of the device lumen. In lines 11, 14, " applicant is requested to be consistent and refer to "the least one auxiliary lumen" or "the at least one flexible wall".

Claims 3 and 62 are vague and indefinite because it is unclear what "or" is intended by since there could be one fluid reservoir and more proximal ends. It is unclear what situation(s) is possible. Further it is unclear how you can have more proximal ends when you may only have at least one auxiliary lumen.

Claims 4 and 64 are vague and indefinite because it is unclear how the main channel and auxiliary channel can be diverging from the outer tube when it is part of the junction housing.

Claims 6, 66 are vague and indefinite because it is unclear how the device lumen valve can be adjacent the proximal end of the device lumen as set forth in claim

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5 be positioned at the external end of the device channel. It is unclear whether there are two device lumen valve involved. "The device lumen valve" lacks proper antecedent basis in line 3.

Claims 7 and 67 is vague and indefinite because it is unclear how the main channel continues from the distal end when it connects at the proximal end of the outer tube. Further it is unclear what is meant by "past the device channel".

Claims 8, 32,68 are vague and indefinite because it is unclear how the material of the junction housing can be more rigid than the junction housing.

Claim 9 is vague and indefinite because it is unclear whether this is the same lumen valve or in addition to the lumen valve set forth in claim 5. "the device lumen valve" in line 3-4 lacks proper antecedent basis.

Claims 10, 70 are vague and indefinite because it is unclear how the main channel continues from the distal end when it connects at the proximal end of the outer tube. Further it is unclear what is meant by "past the device lumen" since the device lumen is part of the outer tube and not part of the junction housing. Further, it is unclear what opening in the junction housing applicant is referring to.

Claim 20 is vague and indefinite because "the two auxiliary lumens" lacks proper antecedent basis. Applicant is suggested to write "the at least two auxiliary lumens".

Claim 21 is vague and indefinite because "the auxiliary lumen", "the flexible wall", "the device" in line 1-3 lacks proper antecedent basis. Applicant is suggested to write "the at least one auxiliary lumens", "the at least one flexible wall". It is unclear what "the

device" is . It is unclear whether applicant intended it to be the device lumen or the multiple lumen access device or another element.

Claim 22 is vague because it is unclear whether "the flexible wall" should be "the at least one." Applicant is recommended to be consistent. It is unclear how the at least one flexible wall can form the inner tube. Unless this is meant to be a coaxial tube.

Claim 23 is vague and indefinite because it is unclear whether there are two inner walls in addition to the at least one flexible wall. Or whether there is one inner wall.

Claim 28 is vague since "the flexible wall", "the auxiliary lumen" in lines 1, 3 lacks proper antecedent basis.

Claim 29 is vague since "the flexible" wall" lacks proper antecedent basis.

Claim 30 is vague and indefinite because it is unclear how the main and auxiliary channel can diverge from the outer tube since it part of the junction housing.

Claim 33 is vague and indefinite because it is unclear what the cavity is. If the cavity is the inside of the junction housing then it is unclear how the lumen valve can be in the cavity, It is unclear whether the lumen valve should be in the outer most of the only the device channel.

Claims 37 and 60 are vague and indefinite. See claim 1.

Claim 61 is vague since "the auxiliary lumen lacks proper antecedent basis. ("at least one .." is recommended.)

Claim 77 is vague and indefinite because it is unclear whether there are two flexible walls in addition to the at least one flexible wall set forth in claim 60 or whether there is only one additional wall.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-7, 17, 21-24, 26-29, 30-33, 37, 60-67, 69-70, 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant (U.S. Patent No. 5,472,418).

Palestrant discloses an outer tube (46) See figs. 1-3, 4-9, 10-12. Palestrant specifically fig. 12 shows 2 auxiliary lumen and device lumen. The medical device being the guidewire (50). The flexible wall being 32 and 38. See col. 10.

10. Claim 1-3, 17-18, 20-24, 26,28-30, 37,60, 62, 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Young (U.S. Patent No. 5,451,206).

See figs. 1-3, 5-6, 7, 8, 12-16. Young discloses in fig. 8 the lumens ending at different location between the proximal and distal end of the outer tube. See fig. 3, 15, col. 14. Young teaches different materials with different durometers depending on what is required of the strength of the lumens.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 8-10, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palestrant (U.S. Patent No. 5,472,418) in view of Nishijima et al. (U.S. Patent No. 5,092,846)

Palestrant teaches all the limitations of the claims except for the specifics of the device lumen valve. Nishijima et al. teaches a valve device in the analogous art of medical introducers. Nishijima et al. teaches a multi component valve insert as shown in figs. 4-5. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teaching of Palestrant with the valve insert teaching of Nishijima et al. in order to provide any leakage of fluids from the body which would endanger the patient.

Conclusion

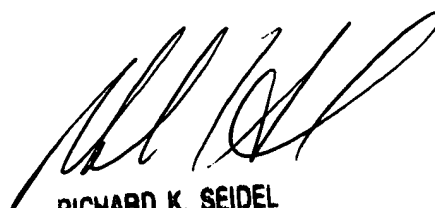
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038.

If attempts to reach the examiner by telephone are unsuccessful, Richard Seidel, can be reached on (703) 308-5115. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703)308-0858.

LoAn H. Thanh
Patent Examiner
Art Unit: 3763
Date: March 26, 2001



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